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10/529,341	02/13/2006	Roclof Johannes Hendrik Kruisinga	13650PCTUS	8991
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KALOW & SPRINGUT LLP 488 MADISON AVENUE 19TH FLOOR NEW YORK, NY 10022			EXAMINER JAVANMARD, SAHAR	
			ART UNIT	PAPER NUMBER
			1617	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/529,341

Applicant(s)KRUISINGA, ROELOF JOHANNES
HENDRIK**Examiner**

SAHAR JAVANMARD

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/18/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

This Office Action is in response to applicant's remarks filed on 4/14/08. Claim(s) 1-12 are pending. Claim(s) 10-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant's election with traverse of the restriction requirement in the reply is acknowledged.

The traversal is on the grounds that the Examiner has not demonstrated that examining the claims together would pose undue burden. The restriction of the groups, however, is not persuasive. It is noted that while the searches of Groups I, II and III may be overlapping, there is no reason to believe that the searches would be coextensive. Accordingly, a search for the groups would pose an undue burden on the Office.

The requirement is deemed proper and is therefore made FINAL. Claim(s) 1-9 are examined herein insofar as they read on the elected invention.

Objections

Claims 1 and 8 contain random numbers in the claims, (i.e., claim 1 "...human 5 being"; claim 8 "...melatonin 30 are..."). Appropriate correction is required.

Claim Rejections - 35 USC § 112.1

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-9 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the treatment of ADHD, does not reasonably provide enablement for the prevention of ADHD as recited in these claims.

The instant claims are drawn to a pharmaceutical composition and a method for the prevention of ADHD. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl's 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The instant invention pertains to a method for the prevention of ADHD.

The state of the prior art:

The skilled artisan would view that the prevention of one or more symptoms of ADHD totally, absolutely, or permanently, is highly unlikely, since one cannot guarantee that the ADHD will always be prevented.

The relative skill of those in the art:

The relative skill of those in the art is very high.

The predictability or lack thereof in the art:

The skilled artisan would view that the treatment to prevent ADHD, absolutely, or permanently is highly unpredictable.

The amount of direction or guidance presented and the presence or absence of working examples:

In the instant case, no working examples are presented in the specification as filed showing how to prevent ADHD totally, absolutely, or permanently. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

Genentech, Inc. v. Novo Nordisk, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful

conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test the combination in the instant claims whether preventing ADHD totally, absolutely, or permanently.

Claim Rejections - 35 USC § 112.2

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 provides for the use of methylphenidate and melatonin, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "melatonin analogue" in the instant claims is a relative term which renders the claim indefinite. The term "melatonin analogue" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The applicant should give specific compounds or substances that according to the specification, "exhibit high affinity for melatonin receptors" (see page 4 of specification).

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "analogues of such hormones" and "analogues of such phyto-hormones" are vague and indefinite. The applicant should give specific compounds or substances of "analogues of such hormones" and "analogues of such phyto-hormones".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glatt (US Patent No. 6,242,446).

Examiner respectfully notes that the "use" claims are being treated as method claims.

Glatt teaches the administration of tachykinin receptor antagonists as useful treatments for attention deficit disorder optionally associated with hyperactivity in a patient (abstract, column 33, lines 4-5). Additionally, Glatt teaches that the tachykinin receptor antagonists can be given in combination with other compounds, including melatonin and methylphenidate among other compounds and any combinations thereof (column 33, lines 21-22).

Further, Glatt teaches that appropriate dosage levels of the active ingredients range from 0.01µg to 50mg orally and via i.v. (column 34, lines 9-30) and can be

developed as solid oral formulations.

Glatt does not specifically teach melatonin together with methylphenidate. Additionally, Glatt does not teach a controlled release formulation or the order in which each component is administered if it is not simultaneous.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined a tachykinin receptor antagonist with methylphenidate and melatonin. One would have been motivated to formulate such a composition because both methylphenidate and melatonin are taught to be combined with a tachykinin receptor antagonist. Therefore, since methylphenidate and melatonin, individually, in combination with a tachykinin receptor antagonist can be used to treat ADHD, then the combination of the three together can be employed to treat ADHD. Furthermore, because the claim limitations recite "open-ended" language such as comprise, the composition can consist of more than just methylphenidate and melatonin.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have prepared the combination in a controlled release formulation. The motivation for preparing a controlled release formulation is to increase the efficacy and bioavailability of the combination. Such formulations are considered to be prima facie obvious.

Additionally, the order and time in which each component is given are deemed to be manipulatable parameters practiced by a person skilled in the art to obtain the best possible formulations.

Conclusion

Claims 1-9 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sahar Javanmard whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

Application/Control Number: 10/529,341
Art Unit: 1617

Page 10

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617